

REMARKS

Claims 21-30 remain in this case for consideration. Claims 21, 23-25 and 26 have been amended to better define Applicant's invention.

A. Prior Art Rejections

1. The Invention

Applicant has invented a method of posterior surgery for replacing fibrocartilage in damaged vertebral discs. In the posterior approach to spinal disc surgery, one makes the surgical incision(s) in the back of the patient. By contrast, in the anterior approach to spinal disc surgery, one makes the surgical incision in the front of the patient, typically in the abdominal region. Unlike existing anterior spinal disc surgeries, permanently articulating vertebral implant devices are inserted using Applicant's method through one or more minimally invasive posterior incisions near the site of the damaged vertebral disc. After an incision is made in Applicant's process, a partial discectomy is posteriorly performed to remove damaged fibrocartilage disc tissue. After the discectomy, at least two permanently articulating vertebral implant devices are posteriorly inserted to replace the disc tissue and permanently allow continued movement of the vertebrae with respect to one another in a way which generally approximates a healthy disc. To avoid damage to spinal nerve tissue and provide necessary balance, at least one vertebral implant device is inserted on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

2. The Cited Art Distinguished

Applicant's claims 21, 22 and 26-30 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Michelson's U.S. Patent No. 6,814,756 B1 ("Michelson patent"). Like the previously cited Peckett article, the Michelson patent discloses a device and accompanying process which is used to *fuse* two vertebrae together. As stated in the first paragraph of Michelson's "Field of the Invention" section, the purpose of Michelson's fusion implants and implant process is to achieve an "immobilization of vertebrae." (Michelson patent, col. 1, ln. 16). Michelson accomplishes this "immobilization" by creating a hollow implant with numerous openings 110 to allow bone to grow into the implant device. (see, Michelson patent, col. 11, lns. 53-58). Michelson then packs his implants "full of bone or other fusion promoting substances" to allow the superior and inferior vertebrae to fuse together through and around Michelson's implant devices. (Michelson patent, col. 4, lns. 30-38). While there is degree of articulating movement in Michelson's implant devices prior to surgery, that movement comes to a desired end when the bone grows through and around Michelson's implant devices as the patient recovers from surgery. *Id.*

Both the previously cited Peckett article and presently cited Michelson patent teach away from Applicant's invention. See *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed.Cir. 2001)(prior art references which "teach away cannot serve to create a prima facie case of obviousness"). Unlike the Peckett and Michelson fusion devices and processes, it is not Applicant's objective to fuse two vertebrae together through and around an implant device so that relative movement between them is prevented. The objective of Applicant's process is exactly the opposite. By using permanently articulating vertebral implant devices, Applicant's process

results in the placement of devices between the respective vertebrae which permanently allows continued movement of the vertebrae with respect to one another in a way which generally approximates a healthy disc.

While a posterior approach was previously known for fusion surgery, as acknowledged by Applicant is his August 23, 2006 Amendment and illustrated by the Michelson patent, this posterior approach was thought to be unavailable for arthroplasty (i.e., the insertion of permanently articulating implant devices). As explained in the declaration which accompanied Applicant's August 23, 2006 Amendment from William A. Brennan M.D., F.A.C.S., a neurosurgeon certified by the American Board of Neurological Surgery who has performed over two thousand spinal surgeries, it was commonly thought in the arthroplasty art that implanting two or more permanently articulating devices side-by-side, as disclosed in the present application, would not work because the two side-by-side devices would inhibit axial rotation. (Brennan Decl., ¶ 8). Such inhibition was considered to be a bad thing in the arthroplasty art because it was perceived as contrary to the objective of implanting a device which approximates the natural movement of the replaced disc.

By contrast, the objective of Michelson's fusion implants is to prevent continued movement of the fused vertebrae. For this reason, fusion surgeons do not worry about inhibiting axial rotation and, in fact, they affirmatively try to prevent any type of movement of the vertebrae with respect to one another. As such, to the extent the Michelson patent teaches use of side-by-side implant devices which inhibit axial rotation, this is considered to be a good thing in the fusion art.

Not dissuaded by the conventional wisdom in his arthroplasty art, Applicant observed that in the lumbar region, for example, the facet joints naturally found in the human body act as a type of doorstep to prevent full rotational movement. Applicant also observed that in cases where disc replacement devices have been anteriorly implanted in the lumbar region to allow full axial rotation, patient complications have arisen from excessive axial rotation.

Applicant reasoned that if full rotational movement was not necessary, articulating implant devices could be made smaller and inserted in a way which would inhibit rotational movement. Because of all the bone and nerve obstacles to such a posterior insertion, Applicant further reasoned that it would be best to insert two smaller articulating implant devices around the left and right sides, respectively, of the spinal cord/spinal nerve roots so that there would be an articulating vertebral implant device on each side of the vertical medial plane defined by the spinous process of the superior and inferior vertebrae. By implanting two articulating implant devices in this way, the implant devices could provide support for each side of the spine (i.e., both the left and right sides) and the resulting resistance to rotational movement of the two devices acting together would simulate the body's own resistance through facet joints. For these reasons, Applicant's posterior implant process is able to substantially achieve the arthroplasty art's objective of implanting prosthetics which approximate the disc's natural movement, particularly in the lumbar region, while allowing the surgeon to make his or her incisions much closer to the damaged disc tissue than is possible with the standard anterior approach.

The fundamental differences between Applicant's arthroplasty process and Michelson's fusion process has led to misunderstandings by the Examiner about the structure of

Michelson's fusion devices and Michelson's process for implanting them. For example, in connection with Applicant's claim 22, the Examiner contends that Michelson's specialized blocker/expander 122 corresponds to Applicant's claimed "cushioning member." The purpose of Applicant's cushioning member is to allow continued movement of the vertebrae in a way which generally approximates the replaced disc. By contrast, the purpose of Michelson's blocker/expander is to "maintain the increased height of the implant 100 and resist the collapse of implant 100 to the collapsed implant height." (Michelson patent, col. 10, Ins. 53-54). If Michelson's blocker/expander 122 were made of a flexible "cushioning" material, it would be unable to "maintain the increased height" and "resist the collapse" of the implant. *Id.* Since providing a flexible "cushioning" member is contrary to Michelson's purpose of having the vertebrae fuse to his implant devices as quickly as possible, it is readily apparent that Michelson's blocker/expander 122 is not a "cushioning member."

Similarly, in connection with Applicant's claims 26-30, the Examiner contends, without citation, that the Michelson patent discloses Applicant's claimed channels. The purpose of channels in Applicant's invention is to correctly position Applicant's permanently articulating implant devices against their respective vertebrae so that Applicant's implant devices do not move out of their correct position when they continuously flex. Since there is no continuous flex from Michelson's fusion device after implantation, there is no need for Michelson to worry about making channels to retain their correct positioning. Michelson's fusion devices are simply screwed into the respective vertebrae as well as the intervertebral region between them in a way which fuses the vertebrae together. In carefully reviewing the Michelson patent, Applicant finds

no disclosure of the type of channels claimed by Applicant nor would there be any need for such channels for Michelson's fusion process.

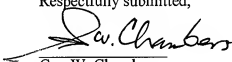
Since the Michelson patent fails to disclose or render obvious Applicant's invention of a method for posterior insertion of a pair of permanently articulating vertebral implant devices placed on each side of a vertical medial plane defined by the spinous process of the superior and inferior vertebrae, the Michelson patent would not render any of Applicant's pending claims unpatentable.

Finally, claims 23-25 have been objected to as being dependent upon a rejected base claim, but indicated to be allowable if rewritten in independent form to include all the limitations of their base claim and any intervening claims. As suggested, Applicant has rewritten claims 23-25 in independent form to include all the limitations of base claim 21 and, as applicable, intervening claim 22.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 576-0200.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Guy W. Chambers", is written over a horizontal line.

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